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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/544,238	02/22/2006	Christopher John Montague Meade	1/1460 PCT	2614
28501	7590	11/07/2006		
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			EXAMINER LUKTON, DAVID	
			ART UNIT 1654	PAPER NUMBER
DATE MAILED: 11/07/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/544,238

Applicant(s)

MEADE ET AL.

Examiner

David Lukton

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 29-36 is/are pending in the application.
- 4a) Of the above claim(s) 29-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25, 35 and 36 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

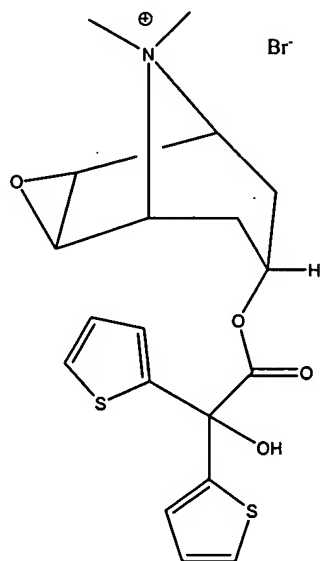
### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Applicants' election of Group I is acknowledged (claims 1-25, 35, 36). Also acknowledged are the elected species; the elected composition contains tiatropium (the anticholinergic), which, in the case of the bromide salt, is the following:



Applicants have argued that a search for the Group 2 invention would require little or no additional effort beyond that which is required for the Group 1 invention. However, applicants are not correct. In the case of the Group 1 invention, the examiner is

required to provide reasons why a skilled drug formulation specialist might want to combine the two agents; a reference may be required to support the argument. By contrast, the Group 2 invention requires no such reasoning or reference. If a bottle containing an anticholinergic happens to be located in close proximity to a bottle containing a TACE inhibitor, the requirements of the Group 2 invention are met. Certainly, if the two bottles were located within 5 inches of one another, this would meet the requirements of claim 12. One could debate, however, whether two bottles that are located 10 feet from one another or 1000 feet from one another would meet the limitations of claim 12, but in any case, the group 2 invention encompasses substantially more subject matter than the Group 1 invention.

Applicants have also suggested that the examiner should state that the method-of-use claims are "subject to rejoinder". Applicants are correct, although the operative phrase here is "subject to". In the event that the composition claims are determined to be allowable prior to the final action, the method claims will simply be rejoined (subject to the same limitations on the composition). In the event that the composition claims are not determined to be allowable until after the final action, the situation becomes more complicated. In the event that the composition claims are not determined to be allowable until after the final action, and in the further event that the method claims would be subject to rejection under 35 USC 112 (first or second paragraph), then rejoinder would not be automatic. For example, claim 33 will not be rejoined in its present form, since the claim makes reference to a published PCT application. Claim

34 may or may not be rejoined in its present form. An inquiry would have to be conducted as to whether in fact all inflammatory and obstructive diseases of the respiratory tract are known to be effectively treated by the allowed compositions. If it were determined that all inflammatory and obstructive diseases of the respiratory tract are known to be effectively treated by the allowed compositions, then rejoining would take place.



A second election requirement is now set forth.

Applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

- a ) a specific counterion of the tiatropium cation (e.g., bromide ion);
- b ) the contents of the elected composition (apart from the anticholinergic and the TACE inhibitor) including all carriers and excipients;
- c ) the "form" of the elected composition, e.g., a solution, a suspension, a powder, a tablet, or a capsule;
- d ) in the <sup>50 f</sup>event that the elected composition is in the form of a powder, election is required the diameter of one of the particles that is present. [Applicants should note that it is physically impossible for one particle to have more than one diameter; thus, election of a single diameter is required, rather than a range].

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER